



NDA 18-896/S-012

Abbott Laboratories
D-389, Bldg. J45-2N
200 Abbott Park Road
Abbott Park, Illinois 60064-6133

Attention: Nicohl R. Wilding
Regulatory Specialist

Dear Ms. Wilding:

Please refer to your supplemental new drug application dated July 25, 2002, received July 26, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Potassium Acetate Injection, USP, in Plastic Vials.

We acknowledge receipt of your submission dated August 16 and October 31, 2002.

This "Changes Being Effected" supplemental new drug application provides for a revised package insert. The WARNINGS and PRECAUTIONS sections are revised to include the statement regarding the aluminum content per the requirements of 21 CFR 201.323.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted July 25, 2002, immediate container and carton labels submitted August 16, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Victoria Kao, Regulatory Project Manager, at (301) 827-7416.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Acting Director
Division of Anesthetic, Critical Care,
And Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Bob Rappaport
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